

REMARKS

Claims 1-29 and 40-45 are subject to restriction, claims 30-39 having been previously canceled.

The Office previously required restriction and election of species. In response, Applicant elected, with traverse, Group I (Claims 1-29), and further elected the following species.

Method: "Group I," characterized as generally drawn to a method of sparing an effective amount of a therapeutic agent administered to a subject having rheumatoid arthritis by administering a therapeutic agent and an effective amount of a sleep restorative agent;

Sleep Restorative Agent: pramipexole (2-amino-4,5,6,7-tetrahydro-6-(propylamino)benzo-thiazole or the (-)-enantiomer thereof), as set forth in claim 9; and

Therapeutic agent: prednisone.

Applicant added new claims 40-45 and identified claims 1-9, 13, 15-22, 25-26, 28-29 and 40-45 as reading on the elected species. In the instant office action, the Examiner made the prior restriction requirement and election of species final.

This third restriction requirement requires further restriction of pending claims 1-29 and 40-45 into one of the following groups:

- 1) active as sleep restorative agents per se; and
- 2) sleep restorative agents which are capable of reducing the amount of a therapeutic agent required to treat arthritis.

Applicant respectfully traverses this restriction requirement as confusing and unnecessarily in view of the prior restriction requirement and election of species. The instant requirement does set forth the claims in each alleged group. (See MPEP § 817.) Thus, it is unclear on the record which claims will be examined. Further, it is not clear whether the instant restriction requirement affects or alters Applicant's prior election of species and designation of claims 1-9, 13, 15-22, 24-26, 28-29 and 40-45 as reading on the elected species. Applicant respectfully requests the Examiner clarify these issues on the record.

Applicant requests the Examiner reconsider the present restriction requirement. The presently claimed invention relates to a method, sleep restorative agent and therapeutic agent

which together comprise a single inventive concept. Under 35 U.S.C. § 121, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (1) the inventions must be independent or distinct as claimed; and
- (2) there must be a serious burden on the examiner if restriction is not required.

*See* MPEP § 803.

The MPEP states that where claims can be examined together without undue burden, the Examiner must examine the claims on the merits even though they are directed to independent and distinct inventions. *See* MPEP §803. In establishing that an “undue burden” would exist for co-examination of claims, the Examiner must show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome. In order to show undue burden resulting from searching difficulties, the Examiner must show that the restricted groups have separate classification, acquired a separate status in the art, or that searching would require different fields of search. According to the MPEP, where the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions. *See* MPEP § 808.02 (C).

In view of the previously required election of species, Applicant believes no undue burden is placed on the Examiner to search the elected species. The office action has not presented any reason why the elected species present an undue burden on the Examiner. Thus, Applicant submits further restriction is improper.

Applicant further traverses the assertion that the alleged inventions have acquired a separate status in the art because of their recognized divergent subject matter. The Office has cited neither patents nor separate fields of search in support of the instant restriction requirement. Thus, the Office has not properly established a basis for a further restriction requirement in this case.

If the Examiner believes a telephone interview would be useful to resolve any issues in this case, the Examiner is welcome to contact the undersigned representative of the Applicant.

Respectfully submitted,

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